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# A REVIEW ON IMMEDIATE REALEASE TABLETS

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## ABSTRACT
Pharmaceutical oral solid dose forms are used wide for many years principally because of their convenience of administration and their quality for delivery for delivery of medicine for general effects. the foremost usually used pharmaceutical solid dose forms these days embody granules, pellets, tablets and capsules. The tablets and capsules will be created directly from powders or from granules pellets, or from film-coated multiple units. Tablets area unit currently the foremost common dose type, accounting for a few seventieth of all moral pharmaceutical preparations created. Tablets could also be outlined as solid pharmaceutical dose forms containing drug substances with or while not appropriate diluents and ready by either compression or molding ways. Hence, tablets will be loosely classified as compressed tablets and formed tablets. Drug having the satisfactory absorption from the oral tissue layer will be developed in such variety of dose type. this text includes demand for orally disintegrating tablets, orally disintegrating films, manduction gums, oral wafers and buccal patches, their benefits, disadvantages, challenges in formulation, patented technologies, numerous technologies developed for developed orally disintegrating dose type, super disintegrating agents within the formulation, analysis technique and numerous marketed merchandise. Tablets area unit unit, compressed solid dose type containing a lively Pharmaceutical Ingredient (API) with or while not excipients. Disintegrate speedily when administration with increased rate of dissolution. the fundamental approach employed indevelopment tablets is that the use of superdisintegrants like Cross coupled Polyvinylpyrrolidone or crospovidone (Polyplasdone), metallic element starch glycolate (Primogel, Explotab), carboxymethylcellulose (Croscarmellose) etc.

**KEYWORDS:** Immediate release, multiple unit, benefits, disintegrates, tablet, capsules.

## INTRODUCTION
Immediate unharness tablets square measure designed to disintegrate and unharness the drug in absence of any dominant options likecoating or alternative formulation techniques. Despite a rising interest in controlled-release drug delivery systems, the foremost common tablets square measure those meant to be enveloped whole, disintegrating and emotional their medicaments quickly within the digestive tube. A Disintegrant may be a substance during a tablet formulation that permits the tablet to interrupt up into smaller fragments upon contact with canal fluids. Such a speedy rupture of the tablet matrix will increase the extent of the pill particles, Thereby increasing the speed of absorption of the active ingredient and manufacturing the required therapeutic action.[1]

Immediate unharness indefinitequantity type permits a manufacturer to increase market exclusivity whereas providing patients a convenient indefinite quantity type or indefinite quantity plan. Immediate unharness Tablets area unit those tablets that area unitdesigned to disintegrate and unharness their medication with no special rate dominant options like special coatings and alternativetechniques, 1, two immediate releases and quick dispersing drug delivery system might supply an answer to those issues. Recently, immediate unharness tablets have started gaining quality and acceptance as a drug delivery system, chiefly as a result of they're simpleto administer, has fast onset of action is economical and cause higher patient compliance. they're additionally a tool for increasingmarkets, extending product life cycles and generating opportunities.[2,3]

Immediate release tablets are those which disintegrate rapidly and get dissolved to release the medicaments. Immediate release may be provided by way of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not prolong to an appreciable extent, the rate of drug release and/or absorption. This term excludes formulations which are adapted to provide for "modified", "controlled", "sustained", "prolonged", "extended" or "delayed" release of drug.[4,5]

The oral route of drug administration is the most popular and successfully used for conventional delivery of drugs. It offers the advantages of convenience, ease of administration, greater flexibility in dosage form design, ease of production, and low cost. The parenteral route of administration is important in case of emergencies, while the topical route of drug administration recently employed to deliver drug to the specific part of the body for systemic effect. It is probable that almost 90% of all the drugs are administered by oral route. Tablets are solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated. The particles consist of one or more active substances with or without excipients such as diluents, binders, disintegrating agents, glidants, lubricants, substances capable of modifying the behavior of the preparation in the digestive tract coloring matter authorized by the competent authority and flavoring substances. The dosage form available for oral administrations are solutions, suspensions, powders, tablets and capsules. The physical state of most of the drugs being solid, they are administered in solid dosage form.

The drugs administered by oral route are versatile, flexible in dosage strength, relatively stable, present lesser problem in formulation and packaging and are convenient to manufacturer, store, handle and use. Solid dosage forms provide best protection to drugs against temperature, light, oxygen and stress during transportation.

An immediate release dosage form allows a manufacturer to extend market exclusivity, while offering patients a convenient dosage form or dosage regimen. Immediate Release Tablets are those tablets which are designed to disintegrate and release their medication with no special rate controlling features, such as special coatings and other techniques, Immediate release and fast dispersing drug delivery system may offer a solution to these problems. Recently immediate release tablets have started gaining popularity and acceptance as a drug delivery system, mainly because they are easy to administer, has quick onset of action is economical and lead to better patient compliance. They are also a tool for expanding markets, extending product life cycles and generating opportunities.[6,7,8,9]

**Advantages of tablets**

- They are unit dosage form, and they offer the capabilities of all oral dosage forms for the dose precision and the least content variability during dosing
- Accuracy and uniformity of drug content
- Optimal drug dissolution and hence, availability from the dosage form for absorption consistent with intended use (i.e., immediate or extended release).
- Usually taken orally, but can be administered sublingually, rectally or intravaginally.
- Their cost is lowest of all oral dosage forms
- They are the most compact of all oral dosage forms
- They are in general the easier and cheaper to package and ship as compare to other oral dosage forms
- Product identification is simple and cheap, requiring no additional processing steps when employing an embossed or monogrammed punch face
- They are ease to administer, does not require a specialist
- They are better suited to large-scale production than other unit oral forms
- They have the better properties of chemical, mechanical and microbiological stability

**Disadvantages**[2]

- Some drugs resist compression, due to their amorphous nature or low-density
- Drugs having bitter taste, objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating of tablet
- Bioavailability problems.
- Chance of GI irritation caused by locally high concentrations medicament.
- Difficulty in swallowing tablets in a small proportion of people and so size and shape become important considerations.
- Slow onset of action as compared to parenterals and solutions

**Types and Classes of Tablets**

Tablets are classified by their route of administration or functions

1) Oral tablets for ingestion

Compressed tablets or standard compressed tablets

- Multiple compressed tablets (MCT)

a) Layered tablets

b) Compression coated tablets

- Repeat action tablets
- Sustained release or modified release tablets
- Delayed action or enteric-coated tablets
- Film coated tablets
- Chewable tablets

2) Tablets used in oral cavity

- Buccal tablets
- Sublingual tablets
- Troches and lozenges
- Dental cones

3) Tablets administered by other routes

- Implantation tablets
- Vaginal tablets

4) Tablets used to prepare solutions

- Effervescent tablets
- Dispersible tablets
- Hypodermic tablets

- Tablet triturates
- The pharmaceutical tablet dosage form

Ideal properties of tablets and basic consideration.

Tablets are the most popular solid dosage forms used nowadays, due to ease of manufacture and administration for the patient. About two-thirds of all prescriptions are dispensed as solid dosage forms, and half of these are compressed tablets. Tablet drug delivery system can range from relatively simple immediate-release formulations to complex extended or modified-release dosage forms. A tablet is a mixture of active pharmaceutical ingredient (API) and excipients, usually in powder form, pressed or compacted into a solid. The excipients include binders, lubricants, glidants (flowaids), disintegrants, sweeteners or flavors and pigments. A coating may be applied to hide the taste of the tablet's components, to make the tablet smoother and easier to swallow, and to make it more resistant to the environment, extending its shelf life. Tablets are often stamped with symbols, letters, and numbers, which enable them to be identified. Size of tablet is from a few millimeters to centimeter. Some tablets are in the shape of capsules, and are called "caplets". Excipients are critical to the design of the delivery system and play a major role in determining its quality and performance. They may be selected to enhance stability (antioxidants, UV absorbers), optimize or modify drug release (disintegrants, hydrophilic polymers, wetting agents, biodegradable polymers), provide essential manufacturing technology functions (binders, glidants, lubricants), enhance patient acceptance (flavors), or aid in product identification (colorants). Thus a tablet formulation is not a random combination of ingredients, but rather a carefully throughout, rational formulation designed to satisfy the above criteria. The objectives of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the proper form, at or over the proper time and in the desired location. Beside the physical and chemical properties of medicinal agents formulated as a tablet, it should posses following characteristics.

- Should be an elegant product having its own identity, while being free of defects such as chips, cracks, discoloration, contamination and the like
- Should have the strength to withstand rigors of mechanical shocks encountered in its production, packaging, shipping and dispensing
- Should have the chemical and physical stability to maintain its physical/chemical attributes over time
- It must be able to release the medicinal agents in the body in a predictable and reproducible manner
- Must have suitable chemical stability over a time so as not to allow alteration of the medicinal agents.[10-16]

**Table 1: Some of the Drug Candidates for Orally Disintegrating Tablets.[17-18]**

| CATEGORY | EXAMPLES |
|---|---|
| Anti Diabetics | Glipizide, Tolbutamide, Glibenclamide, Tolazamide, Gliclazide, Chlorpropamide etc. |
| Anti Hypertensive | Mino xid il, Nimodipine, Amlodipine, Terazosine HCl, Prazosin HCl, Diltiazem etc |
| Anti Histamines | Loratadine, Cetrizine, Cinnarizine, Triprolidine, Fe xo fenadine etc |
| Anti Arrhythmics | Quinidine sulphate, Amiodarone HCl, Disopyramide |
| Diuretics | Acetazolamide, Spironolactone, Furosemide, Amiloride, Ethacrynic acid etc |
| Anti Arrhythmics | Quinidine sulphate, Amiodarone HCl, Disopyramide |
| Analgesics | Ibuprofen, Ketoprofen, Diclofenac sodium, Mefenamic acid, Piroxicam, Oxyphenbutazone, Indomethacin etc. |
| Antibacterial agents | Penincillin, Rifampicin, Nalidixicacid, Trimethoprim, Suphacetamide, |
| | Ciproflo xacin, Tetracyclin, Do xycyclin etc. |
| Anti Depressants | Notriptyiline HCl, Trazodone HCl, Amo xap ine, Minaserin HCl etc |
| Corticosteroids | Hydrocortisone, Betamethasone, Beclomethasone, Prednisolone etc. |
| Anti Protozoal agents | Metronidazole, Tinidazole, Benznidazole, Omidazole |
| Anti Helmintics | Mebendazole, Albendazole, Livermectin, Dichlorophen, Thiabendazole, Praziquantal etc. |
| Gastro-intestinal agents | Ranitidine HCl, Famotidine, Cimitidine, Omeprazole, Ondansteron HCl, Domperidone etc. |

## CHALLENGES IN FORMULATING ORALLY DISINTEGRATING TABLETS

### 1] Mechanical strength

1. In order to swallow ODTs to disintegrate in the oral cavity, they are either made of porous or soft molded matrices, which makes tablet friable and difficult to handle and hence requires peel-off blister packing which increases its cost.[19-20]

### 2] Palatability

Since most drugs are unpalatable, orally disintegrating drug delivery system contains medicament in taste masked form.[13] It dissolves in patient oral cavity, thus release the active ingredient which comes in contact with the taste buds.[5]

### 3] Aqueous solubility

Water soluble drugs pose various formulation challenges results in freezing point depression and formation of glassy solids that may collapse upon drying. Such collapse can be prevented by using various matrix forming e xc ipients like mannito.

**4] Amount of drug**

The application for technologies used for ODTs is limited by the amount of drug into each unit dose.[14] The drug dose must be lower than 400mg for insoluble drugs and 60mg for soluble drugs.[12]

**5] Size of tablet**

The easiest size of tablet to swallow is 7-8mm while the easiest size to handle is 8mm. Therefore, tablet size that is easy to handle and easy to take is difficult to achieve.

**6] Hygroscopicity**

Many orally disintegrating dosage forms are hygroscopic in nature.[12,5] Hence they need protection from humidity.

**MECHANISM OF ODTs**

It involves the following mechanism –

1] Incorporation of an appropriate disintegrating agent in the tablet formulation.

2] For rapid disintegration and dissolution of the tablet, water must quickly enter into tablet matrix.

3] Tablet is broken down into smaller particles.

**EXCIPIENTS US ED FOR PREPARATION OF ODTs**

1] Superdisintegrants -It increases the rate of disintegration and dissolution. For the success of orally disintegrating tablet, the tablet having quick dissolving property which is achieved by super disintegrants. Exa mples are- Crospovidone, MCC, Sodium starch glycolate, CMC, Carbo xy methyl cellulose and modified corn starch.

2] Sweeteners and sugar based excipients-Sugar based e xcip ient act as bulking agents. They exhibit high aqueous solubility and sweetness and impart taste masking property. Exa mples are-Aspartame, Sugar derivative, De xtrose, Fructose, Mannitol, Sorbitol, Maltose etc.

3] Flavors-It increases patient compliance and acceptability. Examples are-Vanilla, Citrus oil, Fruit essence, Eucalyptus oil, Clove oil, Peppermint oil etc.

4] Surface Acti ve agents -It reduces interfacial tension and thus enhances solubilization of ODTs. Examples are-Sodiumlaurlysulfate, Sodiumdoecylsulfate, Polyo xyethylene sorbitan fatty acid esters, Polyo xyethylene steartes etc.

5] Binder -It maintains integrity of dosage form. Examples are-PVP, Polyvinylalchol, Hydro xy propyl methylcellulose.

6] Colour-It enhances appearance and organoleptic properties of dosage form. Examples are-Sunset yellow, Red iron oxide, Amaranth.[3]

7] Lubricants -It helps reduces friction and wear by introducing a lubricating film. Examples are-Stearic acid, Magnesium stearte, Zinc stearte, Talc, Polyethylene glycol, Liquid paraffin, Colloidal silicon-di-oxide etc.

8] Fillers-It enhances bulk of dosage form. Examples are- Mannitol, Sorbitol, Xylitol, Calcium carbonate, Magnesium carbonate, Calcium sulfate, Magnesium trisilicate etc.

**TECHNIQUES US ED FOR PREPARATION OF ODT's**

A] Conve ntional techniques : Various conventional techniques are available for preparation of ODT's are-

1] Freeze drying: It is a process in which water is sublimated from the product after freezing. In this heat sensitive drugs and biological are dried at low temperature that allows removal of water by sublimation.[25]

2] Sublimation: In these, inert solid ingredient that volatilized readily was added to other tablet ingredient and mixtu re is compressed into tablets. The volatile material was then removed by the process of sublimation.[19,37]

3] Spray-drying : It produces very fine and highly porous powder. Tablets prepared from spray drying disintegrate within 20 sec when immersed in an aqueous medium.[27]

4] Molding : In these, water soluble ingredients are used to prepare molded tablets so that tablet dissolves rapidly. Molded tablets are very less compact then compressed tablets and exh ibit porous structure for rapid dissolution.

5] Mass-extrusion: It involves softening the active blends using the solvent mixture of water soluble PEG. The granules of bitter tasting drugs are coat by dried cylinders and hence masking their bitter taste.[26,28]

6] Disintegrates addition: Because of its easy implementation and cost effectiveness, it is a popular technique for formulating ODT's. The basic principle involved is addition of superdisintegrants in optimum conc.

7] Direct compression: It is the easiest way of manufacturing tablets. It consists of a limiting number of processing steps, conventional equipments and commonly available e xc ipients. Also it requires few unit operations as compared to wet granulation.[7,20]

B] Patented technologies: Various patented technologies available for preparation of ODT's are-

1] Flashtab Technology: In these, tablets consists active ingredient in the form of micro crystals. It is conventional tableting technology. Prographarm laboratories have patented the flashtab technology.[29]

2] Wow tab Technology: It involves adequate dissolution rate and hardness .It is patented by "Ya manouchi Pharmaceuticals Co". Wow means without water.

3] Flash dose Technology: It requires greater surface area for dissolution. Flash dose tablets consist of self binding shear form matrix termed as "floss". It has been patented by "Fuisz".

4] Durasolv Technology: It is a patented technology of "CIMA" labs. It consists of druf, fillers and lubricant. It requires low amount of active ingredient.[23]

5] Zydis Technology: It involves quick dissolution, increased bioavailability and self-preserving. It involves softening the active blends using the mixture of methanol and polyethylene glycol.

6] Orasolv Technology: It is patented technology of "CIMA" labs. It involves quick dissolution and taste masking of active ingredient.[29,37]

**Table 1: List of Patented Technologies using manufacturing techniques and description.**

| Technology | Basis for technology | Company |
|---|---|---|
| Zydis | Lyophilization | R. P. Scherer Inc. |
| Quicksolv | Lyophilization | Janseen Pharmaceutical |
| Lyoc | Lyophilization | Farmlyoc |
| Flashtab | Multiparticulate Compressed Tablets | Ethypharm |
| Orasolv, Durasolv | Compressed Tablets | Cima Labs Inc. |
| Rapitab | Compressed Tablets | Schwarz Pharma |
| Wowtab | Compressed Molded Tablets | Yamanouchi PharmaTechnologies, Inc. |
| Fastmelt | Molding | Élan Corp. |
| Ziplets | Molding | Eurand |
| Flashdose | Cotton-candy process | Fuisz Technology Ltd. |

**EVALUATION OF ODT's**[21-30]

Various evaluating parameters of ODT's are-

1] Weight variation.
2] Hardness.
3] Friability Test.
4] Disintegration Test.
5] Mechanical strength.
6] Uniformity of dispersion.
7] Wetting time.
8] In-Vitro disintegration time.
9] In-Vitro dissolution time.
10] Stability studies.

**Some super disintegrants are**

1. Sodium Starch Glycolate (Explotab, primogel) used in concentration of 2-8% & optimum is 4%. Mechanism of Action: Rapid and extensive swelling with minimal gelling. Microcrystalline cellulose (Synonym: Avicel, celex) used in concentration of 2- 15% of tablet weight. And Water wicking.
2. Cross-linked Povidone or crospovidone (Kollidone) used in concentration of 2-5% of weight of tablet. Completely insoluble in water.

**Mechanism of Action**: Water wicking, swelling and possibly some deformation recovery. Rapidly disperses and swells in water, but does not gel even after prolonged exposure. Greatest rate of swelling compared to other disintegrants. Greater surface area to volume ratio than other disintegrants.

3. Low-substituted hydroxyl propyl cellulose, which is insoluble in water. Rapidly swells in water. Grades LH-11 and LH-21 exhibit the greatest degree of swelling. Certain grades can also provide some binding properties while retaining disintegration capacity. Recommended concentration 1-5%
4. Cross linked carboxy methyl cellulose sodium (Ac-Di-sol) Croscarmellose sodium:

**CONCLUS ION**

The area of formulating orally disintegrating indefinite quantity forms is aims at increasing the patient compliance and decreasing the disintegration time. It additionally aims of masking the objectionable style of active ingredients. As compared to alternative difficult processes like freeze drying etc., type of orally disintegrating indefinite quantity form is straightforward and overall value of producing is low. The potential of orally disintegrating indefinite quantity type to disintegrate within the rimaoris among seconds, quick onset of action, increasing patient compliance and style masking of active ingredient makes it a lovely drug delivery type. However, an addition of active ingredient in indefinite quantity type like orally disintegrating tablets, orally disintegrating films, oral wafers, buccal patches and chew gums are excepted to supply a extremely acceptable suggests that of delivering drug to geriatric and medical specialty patients. So. in forth returning years oral drug delivery becomes a far common drug delivery.

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